



Grain Processing Corporation

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2150 31 513 114
October 26, 1999

Documents Management Branch
(HFA305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Dear Sir or Madam:

Re: Docket Number 98N-0313 Surgeon's and Patient Examination
Gloves; Reclassification

Grain Processing Corporation (GPC) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) proposed rule on the reclassification of surgeon's and patient examination gloves. As a major manufacturer of Absorbable Dusting Powder, USP, we commend the agency for its efforts to develop uniform standards for the use of starch on gloves.

Glove Performance and Safety

It is our understanding, based on several industry sources, that powder-free gloves in general, and chlorinated gloves in particular are more prone to breakage, pin hole enlargement due to donning difficulties and have a much shorter shelf life. While we were unable to obtain actual numbers of failure, the agency should have access to this information via its Medical Device Reports from the manufacturers.

While any negative reaction from the use of a powdered glove is regrettable, this risk must be balanced with the risk of glove failure. The projected baseline rate of annual reaction incidents to the total population of 0.0001626 does not allow much room for error. If the agency does not have failure rate information, we strongly suggest that this information be obtained before the proposed restrictions are considered further. The agency must insure that the surgeon's and patient examination gloves are safe and suitable for their intended use and will provide an effective barrier against potentially infectious materials and other contaminants. Before we abandon the powdered gloves, it seems prudent to confirm that the replacement technology is better than the current technology.

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Glove Economics

As the support materials document, powder-free gloves are 50% more expensive than regular dusted gloves. This cost increase should be of concern to the agency as access to gloves may be denied to some healthcare workers. In addition, unsafe multiple reuse practices may evolve.

Absorbable Dusting Powder USP Specifications

Another point to consider is that the USP monograph seems out-of-date to today's technology for sterilizing and using gloves. Absorbable Dusting Powder USP has a long safety record. It was a significant improvement over talc and other inorganic glove lubricants. In addition, proper donning practices, including washing of gloves, are important in the minimization of granulomas and bacterial concerns. We also note the specifications for Absorbable Dusting Powder USP are defined by the United States Pharmacopeia.

However, the manufacture and use of gloves have changed significantly since this specification was established. For example, most gloves are now sterilized by irradiation rather than thermally. Almost all gloves are used only once rather than being cleaned and sterilized multiple times. It is suggested that representatives of the FDA and the Pharmacopeia jointly review and determine if the starch specifications could be adjusted to meet today's practices and minimize adverse reaction potential. We would be glad to participate in this meeting.

For example, a lowered pH range (current range 10.0-10.8) would allow a reduction in the amount of magnesium oxide in the absorbable dusting powder. This change would reduce irritation from the high pH and would reduce dustiness caused by the magnesium oxide. This, in turn, would reduce the potential for an allergic reaction to the powder. At present, the high level of magnesium oxide is required to meet the USP specification for pH. A pH range of 7.0-10.8 would allow more flexibility and a safer product. Another example would be a reduced sediment value, read before sterilization. This would result in a starch that is more absorbable in the body without affecting suitability. This may require some slight adjustments in the manufacturing process such as reduced slurry tank temperatures or hold times.

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Grain Processing Corporation appreciates the opportunity to provide comments on the proposed reclassification of surgeon's and patient examination gloves. Thank you for considering our input on this matter.

Sincerely,

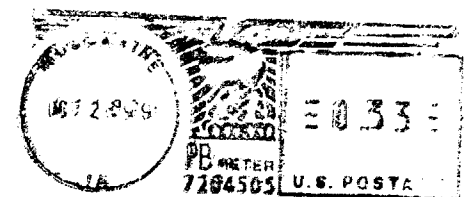
GRAIN PROCESSING CORPORATION

A handwritten signature in dark ink, appearing to read "D. W. Abbott", is written over the printed name.

David W. Abbott
Senior Vice President
for
Rani M. Thomas
Director of Quality and Regulatory Affairs

DWA/dlb


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